DFine
19450 Stevens Creek Blvd., Suite 100
Cupertino, California 95014

AUG 3 0 2006

K061531
PG 1 OF 2

Premarket Notification [510(K)] Summary (per 21 CFR 807.92)

510(k) number _____

1. Submitted by:

DFine, Inc.
19450 Stevens Creek Blvd., Suite 100
Cupertino, CA 95014

Contact Person: Robert D. Poser, DVM
Vice-President, Scientific and Medical Affairs
Telephone: 408-725-1515 ext 224
Facsimile: 408-725-1517

Date Prepared: 30 May 2006

2. Device Name

Trade/Proprietary Name	DFine SPACE CpsXL Bone Cement
Common/Usual Name	Bone Cement for Vertebroplasty
Classification Name	Filler, Bone Cement

3. Predicate Device:

The DFine SPACE CpsXL Bone Cement is substantially equivalent to other bone cements intended for vertebroplasty, including the Mendec Spine bone cement, cleared under 510(k) K042415 by TECRES S.p.A., Verona, Italy.

4. Intended use of the device

The DFine SPACE CpsXL Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

K061531
PG 2 of 2

5. Description of the Device

The DFine SPACE CpsXL Bone Cement is a self-curing polymethyl-methacrylate (PMMA) bone cement intended for use in the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure.

DFine SPACE CpsXL Bone Cement is provided as a two-component system. The powder component of both devices consists of a PMMA polymer with a barium sulphate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter.

6. Summary of the technological characteristics of the device compared to the predicate device.

Documentation is provided which demonstrated the DFine SPACE CpsXL Bone Cement to be substantially equivalent to other legally marketed devices. Both the DFine SPACE CpsXL Bone Cement and the predicate are bone cements intended for use in vertebroplasty, and are similar with respect to chemical composition and fundamental scientific technology. Any differences do not significantly affect the safety and effectiveness of the device.

7. Testing

Physical, chemical and mechanical testing of the DFine SPACE CpsXL Bone Cement has been conducted.

8. Conclusions

Based upon the testing and comparison to the predicate device and commercially available bone cements, the DFine SPACE CpsXL Bone Cement, performs as intended and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2006

Dfine, Inc.
% Dr. Robert D. Poser, DVM
Vice President, Scientific and Medical Affairs
19450 Stevens Creek Boulevard Suite 100
Cupertino, California 95014

Re: K061531
Trade/Device Name: DFine SPACE CpsXL Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: August 18, 2006
Received: August 21, 2006

Dear Dr. Poser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known):

Device Name: DFine SPACE CpsXL Bone Cement

Indications for Use:

The DFine SPACE CpsXL Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma) and malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061531